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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,159	09/27/2001	Rolf Dieter Schraft	SPM-328-B	3931
7590	04/16/2004		EXAMINER	
YOUNG & BASILE, P.C. Suite 624 3001 West Big Beaver Road Troy, MI 48084-3107			BAXTER, JESSICA R	
			ART UNIT	PAPER NUMBER
			3731	13
DATE MAILED: 04/16/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/965,159	SCHRAFT ET AL. <i>(S)</i>	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jessica R Baxter	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 29 January 2004 and 04 February 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-18 and 21-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-18 and 21-31 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### *Drawings*

1. The drawings were objected to as failing to comply with 37 CFR 1.84(p)(4) . Correction is noted and the objection is withdrawn.
2. The drawings were objected to under 37 CFR 1.83(a). Correction is noted and the rejection is withdrawn.

### *Claim Rejections - 35 USC § 112*

3. Claims 1-31 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Correction is noted and the rejection is withdrawn.

### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-5, 7-11, 13, 15-18, 21-22 and 27-31 rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,015,416 to Stefanchik et al.

Regarding claim 1, Stefanchik discloses a device for connecting hollow organs and/or sealing wall defects in hollow organs, having a base mounting (implement 20) which has at least one recess on a first surface (FIG. 10); at least one guidetrack for at least one

spiral needle in which a spiral needle is movable forwards in a rotatable fashion (FIG. 13); and the guidetrack for the spiral needle being disposed at least partially along the edge of the recess in such a manner that the track of the spiral needle during a revolution extends partially in the base mounting and partially in the recess (FIG. 14), the at least two guidetracks (guide 77 and 78) are disposed in the base mounting and, situated opposite each other (FIG. 14), the two guidetracks intersect at least one of the beginning and at the end of their course along the recess, intertwine in each other or extend directly adjacent to each other (FIG. 14).

Regarding claim 2, Stefanchik discloses that the guidetrack in the region at a distance from the recess and/or in the region along the edge of the recess has the configuration of a spiral or of circular segments of a spiral (fig. 14 guides 77 and 78).

Regarding claim 3, Stefanchik discloses that the guidetrack in the region along the edge of the recess has the configuration of circular segments of a spiral, the respective ends of which form openings in the base mounting along the edge of the recess (FIG. 14).

Regarding claim 4, Stefanchik discloses that the guidetrack in the region at a distance from the recess and/or in the region along the recess has the configuration of a spiral or of circular segments of a spiral and has an internal diameter which is greater than or equal to the diameter of a spiral needle (FIG. 14).

Regarding claim 5, Stefanchik discloses that the guidetrack in the region at a distance from the recess is configured as a boring with an internal diameter, which is greater than or equal to the external diameter of the spiral formed by the spiral needle (FIG. 14 and 17).

Regarding claim 7, Stefanchik discloses that along the guidetrack there is disposed at least one roller (rollers 70 and 71), the axis of rotation of which is essentially parallel to the direction of passage of the guidetrack.

Regarding claim 8, Stefanchik discloses that the roller is connected to a drive in a non-positive manner for rotation of the roller (drive 106 and 108).

Regarding claim 9, Stefanchik discloses that the guidetrack in the region outwith the recess along its direction of passage is opened towards the second surface of the base mounting which is situated opposite the first surface (FIG. 17).

Regarding claim 10, Stefanchik discloses that the second surface and the guidetrack, a slot is disposed along the guidetrack (FIG. 17 a slot is on both sides of the base mounting).

Regarding claim 11, Stefanchik discloses that at least along the recess, the surface of the base mounting has a recess for receiving a hollow organ (in between clamp 50).

Regarding claim 13, Stefanchik discloses that the base mounting has a carrier element on its side orientated towards the first surface, which carrier element is mounted rotatably on the base mounting (clip 80, prong 84).

Regarding claim 15, Stefanchik discloses that the carrier element has an annular configuration (FIG. 24).

Regarding claim 16, Stefanchik discloses that the carrier element extends along the external edge of the first surface (FIG. 10 and 11).

Regarding claim 17, Stefanchik discloses that the guidetrack is disposed along the recess in such a manner that the spiral needle can be guided at least partially between two edges of the recess which are situated opposite each other (FIG. 14 and 17).

Regarding claim 18, Stefanchik discloses that the guidetrack is disposed in portions along two edges of the recess which are situated opposite each other in such a manner that the portions of the guidetrack which are disposed along the edges of the recess which are situated opposite each other form segments of a single spiral (FIG. 13 and 14).

Regarding claim 21, Stefanchik discloses that the recess extends from the first to the second surface (FIG. 15 slot in between housings 64).

Regarding claim 22, Stefanchik discloses that the adapter element (FIG. 17) which is configured so as to be engagable at least partially in a form fitting manner from the direction of the second surface into the recess (Clip 80 prongs 82 and 84).

Regarding claim 27, Stefanchik discloses that at least one of the base mounting and the adapter element can be divided into at least two parts along the recess. The device is made of different parts, therefore it can be divided along the recess.

Regarding claim 28, Stefanchik discloses the method for connecting hollow organs and/or for sealing wall defects in hollow organs, characterized in that by using a device according to claim 1, comprising the step of guiding at least one spiral needle in a rotating manner through the adjacent edges of the same or of two different hollow organ openings (Column 9 lines 26-65).

Regarding claim 29, Stefanchik discloses the step on pulling a thread through the edge of the opening of the hollow organ with each spiral needle (stitches 164).

Regarding claim 30, Stefanchik discloses the steps of removing the spiral needle and connecting the thread ends to each other (Column 10 lines 13-20).

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Regarding claim 31, Stefanchik discloses the step of tying the thread ends to each other (Column 10 lines 13-20).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 6, 12 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stefanchik et al. '416 in view of U.S. Patent No. 5,947,983 to Solar et al.

Stefanchik discloses the claimed invention except for the suction openings along the surface of the base mounting. Solar teaches that suction openings are provided to draw in tissue to be sutured (Column 2 lines 1-9). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Stefanchik with the suction openings of Solar in order to draw in tissue to be sutured.

***Response to Arguments***

8. Applicant's arguments filed January 29, 2004 have been fully considered but they are not persuasive.

9. Applicant argues that Stefanchik does not provide the device with intersecting guide tracks. From Figure14, it appears that the guidetracks intersect. Therefore, the rejection is proper.

***Conclusion***

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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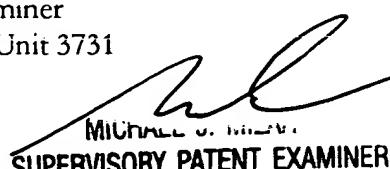
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica R Baxter  
Examiner  
Art Unit 3731

  
MICHAEL J. MILANO  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700

  
JRB